specification at page 7, lines 9–17. No new matter has been added by the amendments to the claims.

Rejections under 35 U.S.C. § 101

Claims 15 and 16 were rejected under 35 U.S.C. § 101 as directed to non-statutory subject matter in their recitation of target cells tranduced or infected by a retroviral vector for use in gene therapy. Claim 15 was also rejected under 35 U.S.C. § 101 for reciting a use without setting forth any process steps. Applicants respectfully traverse this rejection. However, to further prosecution, claim 15 has been amended and no longer recites "target cells tranduced or infected by a retroviral vector for use in gene therapy." Applicants therefore request withdrawal of this rejection.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1 and 13 were rejected under 35 U.S.C. § 112, second paragraph as indefinite for use of the phrase "capable of." While Applicants maintain that the phrase "capable of" is not indefinite, to further prosecution, claims 1 and 13 have been amended and no longer recite this phrase. Applicants therefore request withdrawal of this rejection.

Claim 15 was rejected under 35 U.S.C. § 112, second paragraph as indefinite for use of the phrase "use of a retroviral vector." Applicants submit the amendments to claim 15 overcome this rejection.

Claim 16 was rejected under 35 U.S.C. § 112, second paragraph as indefinite for use of the phrase "target cells." As suggested by the Examiner, claim 16 has been amended to recite the phrase "The target cells." Applicants therefore request withdrawal of this rejection.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 15 and 16 were rejected under 35 U.S.C. § 112, first paragraph as not enabled for the use of any retroviral vector comprising an RNA genome encoding any therapeutic gene located in any intron within the transcription unit of the provirus. Claim 15 has been amended to recite a method for inserting a selected gene into a target cell by contacting the target cell with the retroviral vector according to claim 1. Claim 16 recites a target cell resulting from this method. Applicants respectfully submit that the amendment to the claim 15 overcomes this rejection. Applicants therefore request withdrawal of this rejection.

Rejections under 35 U.S.C. § 102

Yu et al.

Claim 1 was rejected under 35 U.S.C. § 102(b) as anticipated by *Yu et al.* Applicants respectfully traverse this rejection.

The present invention provides a means of inserting into a target cell a selected gene whose expression in the target cell is dependent upon the presence of a factor which enables the transport of an RNA transcript containing the transcribed gene into the cytoplasm. As recited in claim 1, the selected gene is contained within an intron and the expression of the therapeutic gene is regulated by the presence of a polynucleotide response element which is responsive to a nucleus to cytoplasm transport factor. (See disclosure, page 6, line 18–29).

Yu et al disclose an MMLV–based retroviral vector used to deliver RevM10 to human T–cells. According to *Yu et al.*, RevM10 retains the Rev response element (RRE) binding domain and certain properties of wild type Rev. In contrast to claim 1, *Yu et al.* do not teach that the selected gene is contained within an intron of the retroviral vector. Therefore, *Yu et al.* do not disclose the present invention. Accordingly, Applicants respectfully request withdrawal of this rejection.

Cohli et al.

Claims 1–4, 10 and 14 were rejected under 35 U.S.C. § 102(b) as anticipated by *Cohli et al.* Applicants respectfully traverse this rejection.

The claimed invention is described above.

Choli et al. disclose retroviral vectors expressing chimeric RNAs containing HIV–1 RRE and HIV–1 packaging signal in sense and antisense orientations. *Choli et al.* disclose that the Rev–RRE interaction is sufficient to override the inhibitory of *cis* acting repressor sequences (CSR) such that the mRNAs can reach the cytoplasm and become translated (page 20, second paragraph). However, in contrast to the claimed invention, *Choli et al.* do not teach locating the selected gene within an intron. As discussed above, Applicants have found that locating the selected gene within an intron permits the Rev/RRE system to be used to manipulate the expression of the selected gene. Because *Choli et al.* do not disclose the present invention, Applicants respectfully request withdrawal of this rejection.

Lisziewicz

Claims 2, 5–11, 15 and 16 were rejected under 35 U.S.C. § 102(b) as anticipated by *Lisziewicz*. Applicants respectfully traverse this rejection.

The claimed invention is described above.

Lisziewicz describe a non–lentiviral vector incorporating the Rev/RRE system whereby the RRE element is inserted into a retroviral vector or into an intron of a foreign gene contained within that vector. However, *Lisziewicz* does not disclose the presence of the splice donor sequence within the MLV vector or the importance of inefficient splicing. Therefore, *Lisziewicz* does not teach the claimed invention. Applicants respectfully request withdrawal of this rejection.

CONCLUSION

In view of the amendments and remarks made herein, it is respectfully submitted that the application is in condition for allowance. Notification to that effect is earnestly requested.

Respectfully submitted,

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